Docket No.:

CI-0001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of

Wilson BURGESS, William N. DROHAN, Martin J. MACPHEE, David M. MANN and Ewa MADDOX

Serial No.: 09/925,619

August 10, 2001 Filed:

For:

METHODS FOR STERILIZING BIOLOGICAL MATERIALS USING

DIPEPTIDE STABILIZERS

Group Art Unit: 1744

: Examiner: To be assigned

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PATENT

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents Washington, D.C. 20231

Sir:

Pursuant to 37 C.F.R. 1.56, the attention of the Patent and Trademark Office is hereby directed to the reference(s) listed on the attached PTO-1449. One copy of each reference is attached. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the reference(s) be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the indicated date. Applicant reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered. This statement should not be construed as a representation that a search has been made, that information cited in the statement is considered to be and/or is material to patentability, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith. It is further understood that the Examiner will consider information that was cited or submitted to the U.S. Patent and Trademark Office in a prior application relied on under 35 U.S.C. §120. 1138 OG 37, 38 (May 19, 1992).

- This Information Disclosure Statement is being filed (i) within three months of the U.S. filing <u>X</u> date of a U.S. application other than a CPA continued prosecution application under §1.53(d) OR (ii) within three months of the date of entry of the national stage as set forth in §1.491 in an international application OR (iii) before the mailing date of a first Office Action on the merits. No certification or fee is required. 37 C.F.R. §1.97(b).
 - This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection OR Notice of Allowance OR an action that otherwise closes prosecution in the application. 37 C.F.R. §1.97(c).
 - I hereby state that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart

Serial No. 09/925,619 Docket No. CI-0001

foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. 1.97(e)(1).

- b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. 1.97(e)(2).
- c. Attached is our check no. _____ in the amount of \$180.00 in payment of the fee under 37 C.F.R. 1.17(p). Please credit or debit Deposit Account No. 16-0607 as needed to ensure consideration of the disclosed information. Two duplicate copies of this paper are attached.
- 3. This Information Disclosure Statement is being filed after the mailing date of a Final Rejection OR Notice of Allowance OR an action that otherwise closes prosecution in the application, but on or before payment of the Issue Fee. Attached is our check no. ____ in the amount of \$180.00 in payment of the fee under 37 C.F.R. 1.17(p). Please credit or debit Deposit Account No. 16-0607 as needed to ensure consideration of the disclosed information. Two duplicate copies of this paper are attached. 37 C.F.R. §1.97(d).
- a. I hereby state that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. 1.97(e)(1).
- b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. 1.97(e)(2).
- 4. To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 16-0607 and please credit any excess fees to such deposit account.

Respectfully submitted, FLESHNER & KIM, LLP

Mark L. Fleshner

Registration No. 34,596 Donald R. McPhail Registration No. 35,811

Correspondence Address: P.O. Box 221200 Chantilly, VA 20153-1200 Telephone: (703) 502-9440 Date: January 28, 2002 MLF:DRM:kpc

LIST OF PRIOR ART CITED BY			ATTY. DOCKET NO. CI-0001		APPLN. SERIAL NO. 09/925,619		
APPLICANT (PTO-1449)		APPLICANT(S) Wils n BURGESS, William N. DROHAN, Martin J. MACPHEE, David M. MANN and Ew MADDOX					
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EXAMINER'S	*PATENT NO.	*ISSUE DATE	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	NTOR NAME	CLASS	SUBCLASS	FILING DATE
INITIALS	RE. 23,195	02/1950	Arno Brasch	INTOK INAME	CLAGG	GOBOLAGO	DATE
	2,832,689	04/1958	Bernard E. Pr	octor et al	1	5_	-
	2,920,969	01/1960	E.S. Stoddard	· · · · · · · · · · · · · · · · · · ·		180	
<u>.</u>	2,962,380	11/1960	J.H. Werthein			-	/_
***	3,620,944	11/1900	Keiko Tanito	11		W 3 0	En
	3,743,480	07/1973	John D. Falk	****	170	2000	`\
	3,779,706	12/1973	Nablo			7>-	
	4,136,094	01/1979	Condie			100	
	4,251,437	02/1981	1	· al			
	4,282,863	08/1981	Rasmussen et al. Beigler et al.				
***************************************	4,330,626	05/1982	Blair et al.				
	4,550,020		T 50 5 10 10 10 10 10 10 10 10 10 10 10 10 10	FION PUBLICATI	ONS		
	*PATENT	U.S. PATE		A STATE OF THE REAL PROPERTY.			<u> </u>
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EXAMINER'S INITIALS	PATENT NO.	DATE	c	OUNTRY	CLASS	SUBCLASS	Translation Yes N
,	2,056,619	10/1991	Canada				
	0 310 316	04/1989	Europe				
	0 334 679	09/1989	Europe				
	WO 90/00907	02/1990	PCT Int'l.				
	WO 91/16060	10/1991	PCT Int'l.	·			
	WO 95/03071	02/1995	PCT Int'l.				
ОТН	ER ART (Includi	ng Author, T	itle, Date, Perti	nent Pages, Publisl	her, Place of	f Publication, l	Etc.)
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LIST OF PRIOR ART CITED BY			ATTY. DOCKET NO. CI-0001		APPLN. SERIAL NO. 09/925,619		
APPLICANT (PEO 1440)			APPLICANT(S) Wils n BURGESS, William N. DROHAN, Martin J. MACPHEE, David M. MANN and Ewa MADDOX				
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EXAMINER'S		*ISSUE		Prince Services			FILING
INITIALS	*PATENT NO.	DATE		NTOR NAME	CLASS	SUBCLASS	DATE
	4,370,264	01/1983	Kotitschke et a	ıl		-	
	4,409,105	10/1983	Hayashi et al.		<u> </u>	 	
	4,472,840	09/1984	Jefferies		7		
	4,620,908	11/1986	Van Duzer				
	4,784,850	11/1988	Abraham		JAA	3 //	_
	4,798,611	01/1989	Freeman, Jr.		>	0000	Q
	4,933,145	06/1990	Uchida et al.	•	('y	1002	
	4,946,648	08/1990	Dichtelmüller	et al.		100	
	4,963,356	10/1990	Calenoff et al.			90	
	5,000,951	03/1991	Bass et al.				
	5,106,619	04/1992	Wiesehahn et	al.		.	
	5,134,295	07/1992	Wälischmiller	· · · · · · · · · · · · · · · · · · ·	ļ 	ļ <u>. </u>	
	5,185,371	02/1993	Rubinstein	PROFESSION TO SEA PLANTS OF THE SEA	<u> </u>		
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			OREIGN PATENT	DOCUMENTS			
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	TD 4 DT (1 1 1:	A 41 - T	I Data Data	ant Dages Dublishe	n Diago o	Dublication I	'tc)
OTH				nent Pages, Publishe			
Tikvah Alper et al., Protection by Anoxia of the Scrapie Agent and Some DNA and RNA Viruses Irradiated as Dry Preparations, 1968, pps. 157-166, J. gen. Virol., Vol. 3							
	Tikvah Alper et al., Does the Agent of Scrapie Replicate Without Nucleic Acid? May 20, 1967, pps. 764-766, Nature, Vol. 214						
	Tikvah Alper et al., The Scrapie Agent: Evidence Against its Dependence For Replication on Intrinsic Nucleic Acid, 1978, pps. 503-516, J. gen. Virol., Vol. 41						
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APPLICANT APPLICANT APPLICANT APPLICANT APPLICANT Wilson BURGESS, William N. DROHAN, Martin J. MACPHEE, David M. MANN and Ewa MADDOX Filing DATE August 10, 2001 1644	LICT OF DDIOD ADT CITED DV				ATTY. DOCKET NO. CI-0001		o.	APPLN. SERIAL NO. 09/925,619		
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U.S. PATENT DOCUMENTS	A STATE OF THE STA		,				1			
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S,226,065 07/1993 Held et al.	EXAMINER'S			Establish	24		0.655	OUDG: 105		
5,283,034 02/1994 Okrongly et al.	INITIALS				ΝŢ	OR NAME	CLASS	SURCLASS	DA	!E
5,362,442 11/1994 Kent					1					
S,418,130	· · · · · · · · · · · · · · · · · · ·				1.		D			
S,609,864 03/1997 Shanbrom 5,637,451 06/1997 Ben-Hur et al. 5,712,086 01/1998 Horowitz et al. 5,730,933 03/1998 Peterson 5,817,528 10/1998 Böhm et al. U.S. PATENT APPLICATION PUBLICATIONS *APPLN PUB. NO. *PUB. *APPLICANT CLASS SUBCLASS DATE NO. PUB. NO. PUB. NO. PUB. NO. PUB. NO. PUB. NO. POBLICATIONS *APPLN NO. DATE SUBCLASS S							''''			
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5,637,451 06/1997 Ben-Hur et al. 5,712,086 01/1998 Horowitz et al. 5,730,933 03/1998 Peterson 5,817,528 10/1998 Böhm et al. U.S. PATENT APPLICATION PUBLICATIONS *PATENT APPLN PUB. NO. *PUB. *APPLICANT CLASS SUBCLASS DATE U.S. PATENT APPLICATIONS *INVENTOR CLASS SUBCLASS SUBCLAS							- `	r un		
5,712,086 01/1998 Horowitz et al. 5,730,933 03/1998 Peterson 5,817,528 10/1998 Böhm et al. U.S. PATENT APPLICATION PUBLICATIONS *PATENT APPLN. PUB. NO. PUB. APPLICATIONS U.S. PATENT APPLICATIONS U.S. PATENT APPLICATIONS *APPLN. NO. DATE 'INVENTOR CLASS SUBCLASS SUBCLA										
5,730,933 03/1998 Peterson 5,817,528 10/1998 Böhm et al. U.S. PATENT APPLICATION PUBLICATIONS *PATENT APPLN DATE U.S. PATENT APPLICANT CLASS SUBCLASS U.S. PATENT APPLICATIONS U.S. PATENT APPLICATIONS *APPLN DATE *INVENTOR CLASS SUBCLASS *Translation NO. DATE EXAMINER'S INITIALS PATENT NO. DATE COUNTRY CLASS SUBCLASS *Translation No. DATE OTHER ART (Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.) Michael L. Baldwin et al., Irradiation of Blood Components, 1992, pps. 1-78, American Association of Blood Banks R.H. Bassin et al., Abrogation of Fv-1 Restriction With Murine Leukemia Viruses Inactivated by Heat or by Gamma Irradiation, May 1978, pps. 306-315, Journal of Virology, Vol. 26, No. 2 Guy Beauregard et al., Temperature Dependence of the Radiation Inactivation of Proteins, 1985, pps. 117-120, Analytical Biochemistry, Vol. 150								_		
S,817,528 10/1998 Böhm et al. U.S. PATENT APPLICATION PUBLICATIONS *PATENT APPLN. PUB. NO. *PUB. DATE U.S. PATENT APPLICANT U.S. PATENT APPLICATIONS *APPLN. NO. DATE *INVENTOR CLASS SUBCLASS *Translation Translation Translation OTHER ART (Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.) Michael L. Baldwin et al., Irradiation of Blood Components, 1992, pps. 1-78, American Association of Blood Banks R.H. Bassin et al., Abrogation of Fv-1 Restriction With Murine Leukemia Viruses Inactivated by Heat or by Gamma Irradiation, May 1978, pps. 306-315, Journal of Virology, Vol. 26, No. 2 Guy Beauregard et al., Temperature Dependence of the Radiation Inactivation of Proteins, 1985, pps. 117-120, Analytical Biochemistry, Vol. 150			-	······································						
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FOREIGN PATENT DOCUMENTS EXAMINER'S INITIALS PATENT NO. DATE COUNTRY CLASS SUBCLASS No OTHER ART (Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.) Michael L. Baldwin et al., Irradiation of Blood Components, 1992, pps. 1-78, American Association of Blood Banks R.H. Bassin et al., Abrogation of Fv-1 Restriction With Murine Leukemia Viruses Inactivated by Heat or by Gamma Irradiation, May 1978, pps. 306-315, Journal of Virology, Vol. 26, No. 2 Guy Beauregard et al., Temperature Dependence of the Radiation Inactivation of Proteins, 1985, pps. 117-120, Analytical Biochemistry, Vol. 150			l .	U.S. PATENT AP	PI	LICATIONS		<u> </u>		*
FOREIGN PATENT DOCUMENTS EXAMINER'S INITIALS PATENT NO. DATE COUNTRY CLASS SUBCLASS No OTHER ART (Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.) Michael L. Baldwin et al., Irradiation of Blood Components, 1992, pps. 1-78, American Association of Blood Banks R.H. Bassin et al., Abrogation of Fv-1 Restriction With Murine Leukemia Viruses Inactivated by Heat or by Gamma Irradiation, May 1978, pps. 306-315, Journal of Virology, Vol. 26, No. 2 Guy Beauregard et al., Temperature Dependence of the Radiation Inactivation of Proteins, 1985, pps. 117-120, Analytical Biochemistry, Vol. 150		*APPLN.	*FILING	1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 -		in the Marine	- i-e			
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by Gamma Irradiation, May 1978, pps. 306-315, Journal of Virology, Vol. 26, No. 2 Guy Beauregard et al., Temperature Dependence of the Radiation Inactivation of Proteins, 1985, pps. 117-120, Analytical Biochemistry, Vol. 150		,								
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<u>.</u>	5,881,534	03/1999	Ahlqvist et al						
	5,981,163	11/2999	Horowitz et a			<i>\</i>	FOR		
	5,986,168	11/1999	Noishiki				ECE/	10-	
	6,046,024	04/2000	Burton et al.			J	MN 3 A	<u>SU</u>	
	6,049,025	04/2000	Stone et al.			7	200)	
	6,066,626	05/2000	Yew et al.				7>		
	6,087,141	07/2000	Margolis-Nunno et al.			1700			
	6,120,592	09/2000	Brault et al.						
	6,159,490	12/2000	Deghenghi						
	6,171,549	01/2001	Kent	111111111111111111111111111111111111111					
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OTHER ART (Including Author, Title, Date, Pertinent Pages, Publisher, Place of Publication, Etc.) David R. Brown et al., Antioxidant Activity Related to Copper Binding of Native Prion Protein, 2001, pps. 69-76, Journal of Neurochemistry, Vol. 76									
	P. Brown, The Risk of Blood-Borne Creutzfeldt-Jakob Disease, 1999, pps. 53-59, Advances in Transfusion Safety Dev. Biol. Vol. 102								
	P. Brown et al., Further Studies of Blood Infectivity in an Experimental Model of Transmissible Spongiform Encephalopathy, With an Explanation of Why Blood Components Do Not Transmit Creutzfeldt-Jakob Disease in Humans, November/December 1999, pps. 1169-1178, Transfusion, Vol. 39								
EXAMINER				DA	ATE CONSIDEREI)	-	<u>-</u>	

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	6,187,572	02/2001	Platz et al.			 	
	6,190,855	02/2001	Herman et al.				
	6,197,207	03/2001	Chapman et al	l		FOR	
	6,214,534	04/2001	Horowitz et al	l <u></u>		アレケン	
	6,235,508	05/2001	Sowemimo-C	oker et al.		4W 2 C	-U -
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ОТН	ER ART (Includ	ing Author, T	litle, Date, Pert	inent Pages, Publ	isher, Place	of Publication,	Etc.)
	Paul Brown et a Hamster-Adapt No. 5	al., Effect of C ted Scrapie Vi	Chemicals, Heat, rus, May 1982,	and Histopathologops. 683-687, The	gic Processin Journal of In	g on High-Infect fectious Disease	etivity es, Vol. 14
	D. Droven et al	Models of Trai	tion of Infectivit nsmissible Spon	ty in Blood Compo giform Encephalor	onents and Pl pathy, Septen	asma Derivative nber 1998, pps.	es in 810-816,
	Derwent Public		1469				
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LIST OF PRIOR ART CITED BY APPLICANT PTO-1449)			ATTY. DOCKET NO. CI-0001		APPLN. SERIAL NO. 09/925,619		
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ОТН	ER ART (Includi			nent Pages, Pub	lisher, Place o	f Publication, I	Etc.)
	Derwent Publica						
	Derwent Publica			011.0			
	P. Di Simplicio e Radicals, 1991,					abumin vvitn F	ree
	Duane C. Eichle 9436, The Journ					15, 1987, pps	. 9433-
	Luanne H. Elliot					s by Gamma I	rradiation.
	Oct. 1982, pps	704-708, Jour	nal of Clinical	Microbiology, \	/ol. 16, No. 4		
	Fields et al., Susceptibility of Scrapie Agent to Ionizing Radiation, April 5, 1969, pps. 90-91, Nature, Vol. 222						
	D.A. Haig, Further Studies on the Inactivation of the Scrapie Agent by Ultraviolet Light, 1969, pps. 455-457, J. gen. Virol., Vol. 5						1969, pps.
	H. Hiemstra et al., Inactivation of Human Immunodeficiency Virus by Gamma Radiation and its Effect on Plasma and Coagulation Factors, 1991, pps. 32-39, Transfusion, Vol. 31, No. 1						
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The same of the sa	FILING DATE August 10, 2001	GROUP 1744					
OTHER ART (Including Author, Title, Date, Pertine	nt Pages, Publisher, Place	of Publication, Etc.)					
	B. Horowitz et al., Inactivation of Viruses in Labile Blood Derivatives, II. Physical Methods, 1985, pps. 523-527, Transfusion, Vol. 25, No. 6						
1990, pps. 737-740, Can. J. Microbiol.,	Carol House et al., Inactivation of Viral Agents in Bovine Serum by Gamma pradiation, 1990, pps. 737-740, Can. J. Microbiol., Vol. 36						
E.S. Kempner et al., Size Determination pps. 2-10, Analytical Biochemistry, Vol.	E.S. Kempner et al., Size Determination of Enzymes by Radiation Inactivation, 1979, pps. 2-10, Analytical Biochemistry, Vol. 92						
	J.D. Keathley et al., Is There Life After Irradiation? Part 2: Gamma-Irradiated FBS in Cell Culture, July/August 1993, pps. 46-52, BioPharm						
A.D. Kitchen, Effect of Gamma Irradiati Human Coagulation Proteins, 1989, pps		-					
• • • • • • • • • • • • • • • • • • • •	Raymond Latarjet, Inactivation of the Agents of Scrapie, Creutzfeldt-Jakob Disease, and Kuru by Radiations, 1979, pps. 387-407, Slow Transmissible Diseases of the Nervous System, Vol. 2						
R. Latarjet et al., Inactivation of the Scra Light, September 26, 1970, pps. 1341-13		chromatic Ultraviolet					
Prion Protein and Transmissible Spongi	Douglas C. Lee et al., A Direct Relationship Between the Partitioning of the Pathogenic Prion Protein and Transmissible Spongiform Encephalopathy Infectivity During the Purification of Plasma Proteins, April 2001, pps. 449-455, Transfusion, Vol. 41						
	Susan F. Leitman, Use of Blood Cell Irradiation in the Prevention of Posttransfusion Graft-vs-Host Disease, 1989, pps. 219-232, Transfus. Sci., Vol. 10						
	Linda Marton et al., Disinfection and Inactivation of the Human T. Lymphotrogic Virus Type III/Lymphadenopathy-Associated Virus, August 1985, pps. 400-403, The Journal of Infectious Diseases, Vol. 151, No. 2						
	S.I. Miekka et al., New Methods for Inactivation of Lipid-enveloped and Non-enveloped Viruses, 1998, pps. 402-408, Haemophilia, Vol. 4						
Z. Mark Plavsic et al., Resistance of Por 2001, pps. 32-36, BioPharm	Z. Mark Plavsic et al., Resistance of Porcine Circovirus to Gamma Irradiation, April 2001, pps. 32-36, BioPharm						
Pollard, The Effect of Ionizing Radiation	n on Viruses, pps. 65-71						
EXAMINER D	DATE CONSIDERED						

		OTTEST TO			
TOTAL OF PRIOR ART CITED BY	ATTY. DOCKET NO. CI-0001	APPLN. SERIAL NO. 09/925,619			
PTO-1449)	APPLICANT(S) Wils n BURGESS, William N. DROHAN, Martin J. MACPHEE, David M. MANN and Ewa MADDOX				
JAN 10 1119)	FILING DATE	GROUP 1744			
Te most	August 10, 2001				
OTHER ART (Including Author, Title, Date, Pertine) Elena Quaglio et al., Copper Converts the Species That Is Distinct From the Scrapi Journal of Biological Chemistry, Vol. 27 Brian D. Reid, The Sterways Process: a	ne Cellular Prion Protein late Isoform, April 6, 2001, 76, No. 14 New Approach to Inactiv	pps. 11432-11-38, The			
Gamma Radiation, 1998, pps. 125-130,	Biologicals, Vol. 26	20			
Robert G. Rohwer, Estimation of Scrapi Virus Sensitivity to Ionizing Radiation, 6060	e Nucleic Acid MW Fror March 27, 1986, pp. 381,	Nature, Ver 320, No.			
Robert G. Rohwer, Scrapie Infectious A Inactivation, April 12, 1984, pps. 658-60	62, Nature, Vol. 308				
R.G. Rohwer, The Scrapie Agent: "A V Topics In Microbiology and Immunolog	gy, Vol 172				
Robert G. Rohwer et al., Scrapie - Virus Laboratory of Central Nervous System S Communicative Disorders and Stroke, N	Studies, National Institute	es of Neurological and			
Robert G. Rohwer, Virus-Like Sensitivi February 10, 1984, pps. 600-602, Science	ity of the Scrapie Agent to	o heat Inactivation,			
Robert Sullivan et al. Inactivation of Th 61-65, Applied Microbiology, Vol. 22,	iirty Viruses by Gamma F	Radiation, July 1971, pps.			
Boon-Seng Wong et al., Copper Refold Biochemical and Biophysical Research	ing of Prion Protein, 2000	0, pps. 1217-124, 76			
Boon-Seng Wong et al., Differential Co Prion Protein in Vivo, 2000, pps. 136-1 Communications, Vol 273	Boon-Seng Wong et al., Differential Contribution of Superoxide Dismutase Activity by Prion Protein in Vivo, 2000, pps. 136-139, Biochemical and Biophysical Research				
Boon-Seng Wong et al., Prion Disease: 252, Biochemical and Biophysical Research	Boon-Seng Wong et al., Prion Disease: A Loss of Antioxidant Function? 2000, pps. 249-252, Biochemical and Biophysical Research Communications, Vol. 275				
D.E. Wyatt et al., Is There Life After In Contaminants, June 1993, pps 34-39, B	D.E. Wyatt et al., Is There Life After Irradiation? Part I: Inactivation of Biological				
License Amendment and Procedures for Gamma Irradiation of blood Products, June 22 1993, pps. 1-18, Dept. of Health & Human Services, Food and Drug Administration					
	DATE CONSIDERED				

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LISTOF PRODUCTION ART CITED BY APPLICAN	T CI-0001	KET NO.	APPLN. SERIAL NO. 09/925,619			
LIST OF PRIOR ART CITED BY APPLICAN PTO-1449)	APPLICANT(S) Wils n H. BURGESS, William N. DROHAN, Martin MACPHEE, David M. MANN and Ewa MADDOX					
The state of the s	FILING DATE August 10,	2001	GROUP 1744			
OTHER ART (Including Author, Title, Date, Per	tinent Pages, Pu	blisher, Place	e of Publication, Etc.)			
M.F. Alladine et al., γ-Radiation Damage t Letters to the Editor	o Starr-Edwards Val	ves, March 16,	1968, pp. 68, The Lancet,			
Ch. Baquey et al., Radiosterilization of Alb Biomaterials, Vol. 8			`CX.			
Edward H. Bedrossian, Jr., HIV and Banke Reconstructive Surgery, Vol. 7, No. 4						
Liu Bingci, Mouse Antibody Response Foll Placenta Collagen, June 1994, pps. 100-103						
E.A. Borisov et al., Protein Degradation Du Dexamethasone, 1990, pps. 519-521	ring Interphase Dear	th of Thymocyte	es that ed by Radiation and			
R.G. Burwell, The Fate of Freeze-Dried Bo Proceedings, Vol. VII, No. 2, Supplement 1		.976, pps. 95-11	1, Transplantation			
	L. Callegaro et al., Hollow Fiber Immobilized L-Asparaginase: In Vivo and In Vitro Immunological Studies, 1983, pps. 91-96, The International Journal of Artificial Organs, Vol. 6, No. 2					
G. Campalani et al., Aortic Valve Replacen Eur. J. Cardio-thoracic Surgery, Vol. 3	nent With Frozen Irra	adiated Homogr	rafts, 1989, pps. 558-561,			
	David T. Cheung et al., The Effect of γ-Irradiation on Collagen Molecules, Isolated α-chains, and Crosslinked Native Fibers, 1990, pps. 581-589, Journal of Biomedical Materials Research, Vol. 24					
David J. Cohen et al., The Fate of Aortic V. 1988, pps 482-484, Chest, Vol. 93, No. 3	alve Homografts 12	to 17 Years Afte	er Implantation, March			
A.G. Chuchalin et al., Clinical Immunosorb 1529, All Union Research Institute of Chen						
P. De Deyne et al., Some Effects of Gamma Connective Tissue Research, Vol. 27	Irradiation on Patel	lar Tendon Allo	ografts, 1991, pps. 51-62,			
E.A. Dyskin et al., Hemomicrocirculatory E Tract at Portal Hypertension, pps. 68-73	sed in the Wall of Ho	ollow Organs of	the Dog Gastrointestinal			
R. Guidoin et al., A Compound Arterial Pro Healing and Stability of Albuminated Polye	sthesis: The Importa ster Grafts, March 1	nce of the Steri 985, pps. 122-1	lization Procedure on the 28, Biomaterials, Vol. 6			
Ph. Hernigou et al., Radiation Sterilization Chirurgie Orthopedique, Vol. 79	of Bone and the HIV	Virus, 1993, p	ps. 445-451, Revue de			
	Hsing-Wen Sung et al. Effects of Various Chemical Sterilization Methods on the Crosslinking and Enzymatic Degradation Characteristics of an Epoxy-Fixed Biological Tissue, December 1996, pps. 376-					
James R. Malm et al., An Evaluation of Ao October 1967, pps. 471-477, Journal of Tho						
	James R. Malm et al., Results of Aortic Valve Replacement Utilizing Irradiated Valve Homografts, pps 740-747, Annals New York Academy of Sciences					
EXAMINER	DATE CONSID	ERED	· · · · · · · · · · · · · · · · · · ·			

LENGT DRIOR ART CITED BY	ATTY. DOCKET NO. CI-0001	APPLN. SERIAL NO. 09/925,619					
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TO-1449)	FILING DATE August 10, 2001	GROUP 1744					
OTHER ART (Including Author, Title, Date, Pertin	ent Pages, Publisher, Plac	e of Publication, Etc.)					
W. Oh et al., Mitral Valve Replacement With I 712-721, The Journal of Thoracic and Cardiov	Preserved Cadaveric Aortic Homascular Surgery, Vol. 65, No. 5	nografts, May 1973, pps.					
K. Pietrucha, New Collagen Implant As Dural							
14, British Medical Journal, Vol. 1	Maria Raptopoulou-Gigi et al., Antimicrobial Proteins in Sterilised Human Milk January 1, 1977, pps. 12-14, British Medical Journal, Vol. 1						
Aortic Valve Grafts for Transplantation, Archi	Edward A. Rittenhouuse et al., Sterilization of Aortic Valve Grafts for Transplantation, July 170, pps. 1-5, Aortic Valve Grafts for Transplantation, Archives of Surgery, Vol. 101, Do 1						
H. Sato et al., Sterilization of Therapeutic Imm The International Journal of Artificial Organs,	H. Sato et al., Sterilization of Therapeutic Immunoadsorbents by Ionizing Radiation, 1986, pps. 131-136, The International Journal of Artificial Organs, Vol. 9, No. 2						
Richard A. Smith et al., Gamma Irradiation of Research, Vol. 19	Richard A. Smith et al., Gamma Irradiation of HIV-1, 2001, pps. 815-819, Journal of thopaedic Research, Vol. 19						
Barbara Lüssi-Schlatter et al., Die Antimikrob Gamma-Strahlen, Pharmazeutisches Institut de Galenische Abteilung	elle Behandlung von Peroralen : r Eidgenössischen Technischen	Enzympräparaten mit Hochschule Zürich					
		·					
EXAMINER	DATE CONSIDERED						